

CLAIMS

We claim:

1. A method of forming a bioactive composite coating on a device comprising the steps of:

providing an electrolytic solution comprising metal ions;

contacting the device with the electrolytic solution;

applying an electric charge across the device to form a first layer on the device;

providing an electrochemical solution comprising metal ions and a biologically active agent; and

contacting the device having said first layer with the electrochemical solution to form a second bioactive metal composite layer on the device.

2. The method according to claim 1 wherein the device has a surface and said surface is etched prior to contact with the electrolytic solution.

3. The method according to claim 1 wherein the steps of contacting the device with the electrolytic solution and applying an electric charge across the device, are repeated so as to form another layer intermediate of said first layer and said second bioactive metal composite layer.

4. The method according to claim 1 wherein the electrochemical solution is an electroless electrochemical solution.

5. The method according to claim 1 further comprising the step of forming a top layer over the second bioactive metal composite layer.

6. The method according to claim 5 wherein the top layer comprises a metal.

7. The method according to claim 5 wherein the top layer comprises a polymeric material.
8. The method according to claim 1 wherein the metal ions are selected from the group consisting of ions of nickel, cobalt, copper, gold, silver, platinum, chromium, palladium, and molybdenum.
9. The method according to claim 1 wherein the metal ions in both solutions are the same.
10. The method according to claim 1 wherein the metal ions in the electrolytic solution and the metal ions in the electrochemical solutions are derived from metal salts.
11. The method according to claim 1 wherein the electrochemical solutions further comprises a reducing agent.
12. The method according to claim 10 wherein the reducing agent comprises phosphorous or boron.
13. The method according to claim 1 wherein said biologically active agent is selected from the group consisting of anti-restenosis compounds, anti-inflammatory compounds, anti-thrombogenic compounds, genes and growth factors.
14. A method of forming a composite coating, having one or more therapeutic agents, on an implantable structure comprising the steps of:

providing a first electrochemical solution containing metal ions and a reducing agent;

contacting the implantable structure with said first electrochemical solution to form a first metallic matrix layer on the implantable structure;

providing a second electrochemical solution containing metal ions, a

reducing agent and one or more therapeutic agents; and

contacting the implantable structure, having said first metallic matrix layer, with the second electrochemical solution to form a second metallic matrix layer containing said one or more therapeutic agents on the implantable structure.

15. The method according to claim 13 wherein the first and second electrochemical solutions are electroless electrochemical solutions.

16. The method according to claim 13 further comprising the step of forming a top layer over the second metallic matrix layer.

17. The method according to claim 15 wherein the top layer comprises a metal.

18. The method according to claim 15 wherein the top layer comprises a polymeric material.

19. The method according to claim 13 wherein the metal ions are selected from the group consisting of ions of nickel, cobalt, copper, gold, silver, platinum, chromium, palladium, and molybdenum.

20. The method according to claim 13 wherein the metal ions in the first and second electrochemical solutions are the same.

21. The method according to claim 13 wherein the metal ions in the first and second electrochemical solutions are derived from metal salts.

22. The method according to claim 13 wherein the electrochemical solutions further comprise a reducing agent.

23. The method according to claim 21 wherein the reducing agent comprises phosphorous or boron.

24. The method according to claim 13 wherein said one or more therapeutic agents is one or more substances selected from the group consisting of anti-

restenosis compounds, anti-inflammatory compounds, anti-thrombogenic compounds, genes and growth factors.

25. A method of forming a bioactive composite coating on a device comprising the steps of:

providing an electrolytic solution containing metal ions;

contacting the device with the electrolytic solution;

applying an electric charge across the device to form a first layer on the device;

providing a first electrochemical solution containing metal ions and a reducing agent;

contacting the device with said first electrochemical solution to form a second layer on the device;

providing a second electrochemical solution containing metal ions, a reducing agent and at least one biologically active agent; and

contacting the device, having said first layer and said second layer, with the second electrochemical solution to form a third bioactive metal composite layer on the device.

26. The method according to claim 25 wherein the steps of contacting the device with the electrolytic solution and applying an electric charge across the device, are repeated so as to form another layer intermediate of said first layer and said second layer.

27. The method according to claim 25 wherein the device has a surface and said surface is etched prior to contact with the electrolytic solution.

28. The method according to claim 26 wherein the device has a surface and said surface is etched prior to each step of contact with the electrolytic solution.
29. The method according to claim 25 wherein the first and second electrochemical solutions are electroless electrochemical solutions.
30. The method according to claim 25 further comprising the step of forming a top layer over the third bioactive metal composite layer.
31. The method according to claim 30 wherein the top layer comprises a metal.
32. The method according to claim 30 wherein the top layer comprises a polymeric material.
33. The method according to claim 25 wherein the metal ions are selected from the group consisting of ions of nickel, cobalt, copper, gold, silver, platinum, chromium, palladium, and molybdenum.
34. The method according to claim 25 wherein the metal ions in all solutions are the same.
35. The method according to claim 25 wherein the metal ions in the electrolytic solution and the metal ions in the first and second electrochemical solutions are derived from metal salts.
36. The method according to claim 25 wherein the first and second electrochemical solutions further comprise a reducing agent.
37. The method according to claim 36 wherein the reducing agent comprises phosphorous or boron.
38. The method according to claim 25 wherein said at least one biologically active agent is selected from the group consisting of anti-restenosis compounds, anti-inflammatory compounds, anti-thrombogenic compounds, genes and growth

factors.

39. A method of forming a composite coating, having one or more therapeutic agents, on an implantable structure, having a surface, comprising the steps of:

providing an electrochemical solution containing metal ions and one or more therapeutic agents;

contacting the implantable structure with said electrochemical solution to form a composite coating including a metallic matrix and said one or more therapeutic agents within said metallic matrix; and

wherein the surface of the implantable structure is not sensitized prior to contact with electrochemical solution.

40. The method according to claim 39 wherein the implantable structure does not have a catalyst deposited on the surface prior to contact with the electrochemical solution.

41. A method of forming a bioactive composite coating on a device, having a surface, comprising the steps of:

providing an electrochemical solution containing metal ions and at least one biologically active agent;

contacting the surface of the device with said electrochemical solution to form a bioactive composite coating including a metallic matrix and said at least one or biologically active agent within said metallic matrix;

and wherein the device does not have a catalyst deposited on the surface prior to contact with the electrochemical solution.

42. The method according to claim 41 wherein the surface of the device is not sensitized prior to contact with electrochemical solution.

43. A medical device comprising:
- a substrate having an outer surface; and
 - a composite coating on said outer surface including a plurality of layers which are comprised of:
 - a first metal layer; and
 - a second metallic composite layer comprising a metal and at least one therapeutic material.
44. The medical device according to claim 43 wherein the first metal layer is electroplated on the outer surface of the substrate.
45. The medical device according to claim 43 wherein the metal comprising said first metal layer is selected from the group of metals consisting of nickel, cobalt, copper, gold, silver, platinum, chromium, palladium, and molybdenum.
46. The medical device according to claim 43 wherein the substrate is a metal or a metal alloy.
47. The medical device according to claim 46 wherein the substrate is a metal alloy selected from the group consisting of stainless steel, cobalt-chromium, nickel-titanium, platinum-iridium, and niobium-zirconium.
48. The medical device according to claim 43 wherein the substrate is a stent.
49. The medical device according to claim 43 wherein the least one therapeutic material in said second metallic composite layer comprising a substance which is more radiopaque relative to the substrate.
50. The medical device according to claim 43 further comprising a top layer over the second metallic composite layer.

51. The medical device according to claim 50 wherein said top layer is a metallic layer.

52. The medical device according to claim 51 wherein said top layer is a polymeric material.

53. The medical device according to claim 43 wherein the least one therapeutic material in said second metallic composite layer comprising at least one biologically active substance.

54. The medical device according to claim 53 wherein the least one biologically active substance is selected from the group consisting of anti-restenosis compounds, anti-inflammatory compounds, anti-thrombogenic compounds and growth factors.